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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,865	10/17/2003	T. Wade Fallin	MED-1 CON CIP	9572
44270	7590	08/09/2005	EXAMINER	
MEDICINELODGE INC. 180 SOUTH 600 WEST LOGAN, UT 84321			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER

3738

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,865

Applicant(s)

FALLIN ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 17, 26, 28, 32-35, 38-45, 47-52, 54-59, 64, 73, 75, 79-82, 85-90 and 94-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/25/04</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 6,13-16,18-25,27,29-31,36,37,46,53,60-63,65-72,74,76-78,83,84,91-93 and 100-102.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species 1(c), 2(b), 3(a) and 4(b), claims 1-5, 7-12, 17, 18, 26, 28, 32-35, 38-52, 54-59, 64, 65, 73, 75, 79-82, 85-90 and 94-99, in the reply filed on 5/25/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The examiner has additionally withdrawn claims 18 and 65 because the elected embodiment of the fixation element shown in Figure 28A does not include a post having a non-circular cross-section along at least a portion of its length. Claim 46 is also withdrawn because a single fixation element (elected embodiment shown in Figure 28A) does not and cannot attach both superior and inferior bone contacting elements.
3. Claims 1-102 are currently pending. Claims 6, 13-16, 18-25, 27, 29-31, 36, 37, 46, 53, 60-63, 65-72, 74, 76-78, 83, 84, 91-93 and 100-102 are withdrawn from consideration for being drawn to a non-elected species. The claims being considered for further examination on the merits are claims 1-5, 7-12, 17, 26, 28, 32-35, 38-45, 47-52, 54-59, 64, 73, 75, 79-82, 85-90 and 94-99.

Priority

4. Claims 28 and 75 have an effective filing date of 9/23/03 because the limitation of a spiked washer was not disclosed until the filing of the provisional application 60/505,199.

Specification

5. The disclosure is objected to because of the following informalities: on page 72, line 8, "washed 800" should be changed to --washer 800--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5, 12, 17, 26, 32-35, 38-45, 47-52, 59, 64, 73, 79-82, 85-90 and 94-99 rejected under 35 U.S.C. 102(e) as being anticipated by Reiley (USPN 6,610,091, as cited in applicant's IDS).

Reiley discloses a prosthesis for the replacement of at least a portion of the bone of a superior prosthesis for the replacement of at least a portion of the bone of a superior facet located on a first mammalian vertebra and for replacement of at least a portion of the bone of an inferior facet located on a second mammalian vertebra with all the elements of claims 1, 41, 42, 43, 44, 45, 47 and 85. See Figures 29-33, columns 14-15, lines 48-60 and columns 16-17, lines 38-21 for a superior articulating element (36) that articulates with another facet and a superior bone contacting element (26') that contacts one of a surface of the first vertebra or another element contacting a surface of the vertebra, wherein the superior articulating element (36) is connected to the superior bone contacting element (26'). A first fixation element (37) attaches

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the superior bone contacting element (26') to the first vertebra, wherein the first fixation element (37) is adapted for implantation into an interior bone space of a pedicle of the vertebra. An inferior articulating element (30) articulates with another facet and an inferior bone contacting element (26) contacts one of a surface of the second vertebra or another element contacting a surface of the vertebra. The inferior articulating element (30) is connected to the inferior bone contacting element (26) and a second fixation element (34) attaches the inferior bone contacting element (26) to the second vertebra (see Figure 41). The second fixation element (34) is adapted for implantation into an interior bone space of a pedicle of the vertebra. The prosthesis is configured so that no portion of said prosthesis contacts the posterior arches of said first and second vertebrae. See Figure 33 for the articulating surface comprising a wing ear (26, 26') extending upward from the bone contacting surface (claim 41). See column 15, lines 37-38 for the articulating surface (30) being of a "button" shape, which makes it substantially planar, extending adjacent to the pedicle and extending parallel to the fixation element (34) (claims 42 and 43). See Figure 41 for the fixation element (34) clamping the bone contacting surface (26) to a resected surface of the vertebrae (claim 44).

Claims 2 and 3, see Figure 33. These claims do not structurally limit the claimed prosthesis because the surface of the vertebra is not, and cannot be a claimed element of the invention.

Claims 4 and 5, see Figure 41 for the fixation element (34) comprising a post, which attaches the bone contacting surface (26) to the vertebra by extending through an opening (32) in the bone contacting surface (26), and an enlarged head attached to the post for capturing the bone contacting surface (26) against the surface of the vertebra.

Claims 12 and 17, see Figure 41 and column 15, lines 18-20 for the fixation element (34) being a pedicle screw, which includes a post being threaded on its inner end to facilitate attachment to the vertebra and a circular cross-section.

Claim 26, see column 9, lines 32-37 for a supplemental holding element for holding the fixation element to the vertebra.

Claims 32, 33, 35, 86 and 89, see Figure 33 for a superior facet prosthesis (26') and an inferior facet prosthesis (26), wherein the articulating surface comprises a blade (36).

Claims 34 and 88, see column 15, lines 37-38 for the articulating surface (30) being of a "button" shape, which makes it a blade laterally offset from the opening (32).

Claims 87 and 90, see Figure 33 for the bone contacting element (26') being adapted to contact another element (26) contacting a resected surface of a pedicle.

Reiley discloses a prosthesis (330) for the replacement of at least a portion of the bone of a facet located on a mammalian vertebra with all the elements of claim 38 and 40. See Figure 4 for an articulating surface (325) that articulates with another facet. A bone contacting surface (315) contacts a surface of the vertebra, wherein the articulating surface (325) is connected to the bone contacting surface (315). A fixation element (310) that attaches the bone contacting surface (315) to the vertebra is adapted for implantation into an interior bone space of a pedicle of the vertebra. See Figures 7-10 for the bone contacting surface (315) being configured to engage a resected surface of the vertebra. See Figure 10 for the bone contacting surface (portion of 315 that is actually in contact with the bone) having a smaller surface area than the articulating surface (325) (claim 40).

Claim 39, see Figures 7-10 for the resected surface of the vertebra being recessed relative to the surrounding portions of the vertebra, and the bone contacting surface (315) being configured to engage the recessed surface.

Reiley discloses a method for replacing at least a portion of the bone of a facet located on a mammalian vertebra with all the elements of claims 48 and 94. See Figures 29-33, column 3, lines 8-11, columns 14-15, lines 48-60 and columns 16-17, lines 38-21 for providing an articulating surface/element (36, 34) that articulates with another facet and a bone contacting surface/element (26', 26) that contacts a surface of the vertebra. The articulating surface/element (36, 34) is connected to the bone contacting surface/element (26', 26). A fixation element (37) that attaches the bone contacting surface/element (26', 26) to the vertebra is adapted for implantation into an interior bone space of a pedicle of the vertebra. The prosthesis is configured so that no portion of said prosthesis contacts the posterior arch of said vertebra. The method further comprises positioning the bone contacting surface/element (26', 26) against a surface of the vertebra and attaching the bone contacting surface/element (26', 26) to the vertebra using the fixation element (37, 34).

Claims 49, see Figure 31 for the surface of the vertebra contacted by the bone contacting surface (26) comprising an exterior surface of the vertebra.

Claim 50, see Figures 32 and 33 for the surface of the vertebra contacted by the bone contacting surface (26') comprising a resected surface of the vertebra.

Claims 51 and 52, see rejections to claims 4 and 5, supra.

Claims 59 and 64, see rejections to claims 12 and 17, supra.

Claim 73, see rejection to claim 26, supra.

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Claims 79, 80, 82, 95 and 98, see rejections to claims 32, 33, 35, 86 and 89, supra.

Claims 81 and 97, see rejection to claims 34 and 88, supra.

Claims 96 and 99, see rejections to claims 87 and 90, supra.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 7-11 and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley in view of Mathews (USPN 5,569,248).

Reiley discloses a prosthesis for the replacement of at least a portion of the bone of a facet and a method for replacing at least a portion of the bone of a facet located on a mammalian vertebra with all the elements of claims 4, 5, 51 and 52, but is silent to the enlarged head being selectively attachable to the post, as required by claims 7 and 54, the enlarged head further being a nut adapted to be screwed onto the threaded outer end of the post, as required by claims 8 and 55, the post comprising a non-circular recess having a hexagonal cross-section on its outer end, as required by claims 9, 10, 56 and 57, and the post being cannulated, as required by claims 11 and 58. Mathews teaches a pedicle screw (30) that has an enlarged head in the form of a nut (42) screwed onto the threaded outer end (34) of the post in order to fix a fixation plate (40). The post comprises a non-circular recess having a hexagonal cross-section on its outer end in order to be engaged by an appropriate screw driving tool. The pedicle screw is cannulated (36) in order

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for a guidewire to be inserted therethrough. See Figure 1-3, column 7, lines 55-62 and column 8, lines 7-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Mathews to modify the pedicle screw fixation element (34) of Reiley by having the enlarged head a hexagonal nut screwed onto the threaded outer end of the post in order to fix the bone contacting element (26), including a non-circular recess having a hexagonal cross-section on the outer end of the post in order for it to be engaged by an appropriate screw driving tool, and having the pedicle screw cannulated in order for a guidewire to be inserted therethrough.

10. Claims 28 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley in view of Pagliuca et al. (USPAP 2003/0073998).

Reiley discloses a prosthesis for the replacement of at least a portion of the bone of a facet and a method for replacing at least a portion of the bone of a facet located on a mammalian vertebra with all the elements of claims 26 and 73, but is silent to the supplemental holding element comprising a spiked washer, as required by claims 28 and 75. Pagliuca et al. teaches using a spiked washer (660) with a pedical screw (624) that includes an enlarged head in the form of a nut in order to engage the knurled surface of a spine plate (650). See Figure 26 and [0162]-[0164]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Pagliuca et al. to have the supplemental holding element of Reiley be a spiked washer. Use of a spiked washer would require the bone contacting element (26) to have knurled surface and the enlarged head to be a nut screwed onto a threaded outer end of the post. The spiked washer will engage the knurled surface of the bone contacting

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element (26) such that the nut captures the bone contacting surface (26) against the surface of the vertebra and the spiked washer is captured to the vertebra by the nut. The examiner contends that the spiked washer in combination with the knurled surface of the bone contact element (26) will minimize the chances of the prosthesis rotating around the axis of the pedicle screw fixation element (34) during use.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 45, 48 and 85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 8 of U.S. Patent No. 6,579,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the above cited claims of the current application and the above cited claims of the patent both require an articulating surface, a bone contacting surface, a fixation element and that no portion of the prosthesis contacts the posterior arch of the vertebra.

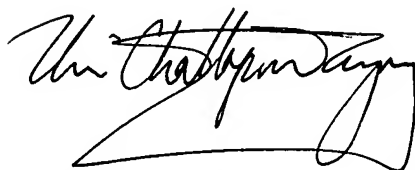
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748.

The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner